

REMARKS / ARGUMENTS

Claims 12-37 are pending. Claims 22-30 have been cancelled, without prejudice, as being drawn to non-elected subject matter.

Claims 31 – 37 are supported, e.g., on page 4, line 25, page 4, line 28, page 5, line 8, page 6, lines 16-17, and by Examples 1-9.

The title of the application has been amended to make it more descriptive, as requested by the examiner. Support for this language is found on page 3, lines 13 - 16.

No new matter is added by this amendment.

Claims Rejections - 35 USC §103

The Examiner has rejected claims 12-21 under 35 USC §103(a) as allegedly unpatentable over Azrolan in view of US Patent No. 5,516,770 ("Waranis") and GB 237611 ("Haeberlin").

The examiner argues that the teaching in Azrolan that a preferred formulation of CCI-779 is taught by Waranis would motivate one of skill in the art to combine the teachings of these documents with the teachings of Haeberlin. The examiner further states that "common knowledge of one of skill in the art would motivate them to determine a suitable preservative/stabilizer for a parenteral formulation, and the teachings of Haeberlin provide such an agent". The examiner argues that Applicants must show that the teachings of Haeberlin do not work through the instant invention mechanism of an antioxidant.

Applicants respectfully disagree that this combination of documents renders the claims obvious.

The examiner argues "common knowledge of one of skill in the art would motivate them to determine a suitable preservative/stabilizer for a parenteral [CCI-779] formulation". However, there is no teaching in the art of any problems associated with CCI-779 parenteral formulations much less the specific problems recognized by the invention. In the absence of a recognition of the problem in the art, there can be no motivation in the art to look for a solution.

The examiner argues that Applicants must demonstrate that the acids of Haeberlin do not function as an antioxidant. However, the mechanism by which

Haeblerlin's acid works is not relevant. It is necessary to take the teachings of the cited documents as a whole, and even if combined, their teachings do not suggest the present invention.

Haeblerlin describes the stabilization of rapamycins and ascomycins (*e.g.*, FK-506) by formulation in 0.05% to 5% acid, by weight of the macrolide composition. As can be seen from the examples, the acid of Haeblerlin's formulation is present in a much higher concentration than is the antioxidant of the present invention. The teachings of Waranis and Azrolan do not provide a parenteral formulation which contains all of the components present in the claimed invention. Further, based on their teachings, there would be no reason to combine what Haeblerlin claims is an acid-stabilized formulation with an alcoholic solvent, an antioxidant, a diluent solvent, and a surfactant.

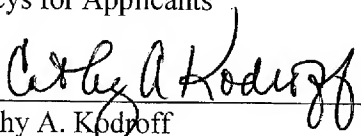
Accordingly, the Examiner is respectfully requested to reconsider and withdraw this ground of rejection.

In view of the amendments presented and the above remarks, the Examiner is respectfully requested to reconsider and withdraw all pending objections and rejections and permit the application to pass to issue.

The Director is hereby authorized to charge any deficiency in any fees due with the filing of this paper, or credit any overpayment in any fees, to Deposit Account Number 08-3040.

Respectfully submitted,
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